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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Allergan PLS Securities Litigation

No. 18 Civ. 12089 (CM)

DECISION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS

McMahon, C.J.:

In this putative securities fraud class action lawsuit, Lead Plaintiff Boston Retirement System (hereinafter referred to as "BRS" or "Plaintiff"), on behalf of itself and all others similarly situated, alleges that Allergan plc ("Allergan" or the "Company") and certain of its senior executives (the "Executive Defendants," and, together with Allergan, the "Defendants") made materially false and misleading statements concerning the purported link between anaplastic large cell lymphoma ("ALCL"), a rare type of blood cancer, and silicone-gel breast implants manufactured by the Company. (*See generally* Consolidated Amended Class Action Complaint ("CAC"), dated Apr. 19, 2019, Dkt. No. 58.) Defendants now move to dismiss the complaint under Fed. R. Civ. P. 12(b)(6). (Mot. to Dismiss, dated May 24, 2019, Dkt. No. 72.)

Plaintiff does not contend (indeed, it admits) that Allergan has, over the years, repeatedly disclosed that there were studies suggesting a "possible" link between implants—including the particular type made by the Company—and ALCL. So, in order to create a securities fraud claim, Plaintiff's complaint asserts that Defendants were required to disclose that there was a "definitive" link between Allergan's breast implant products and ALCL.

The problem is that the complaint does not plausibly allege the presence of such a "definitive" link, so Defendants were not required to disclose one. To that extent, the motion to dismiss should be granted.

But the securities laws do not simply police outright falsehoods; they also protect investors from misleadingly incomplete disclosures. Once a person speaks on a given topic, she has a duty to speak completely and truthfully. Plaintiff also alleges that Defendants did not tell the whole truth about Allergan's breast implant products. Here, they stand on firm ground.

Defendants' motion is granted in part and denied in part.

I. Applicable Legal Standard

The Court's ordinary practice is to recite the factual allegations before laying out the applicable legal standard governing the pending motion. However, in a case like this one—factually rich but subject to the law's more exacting standards for pleading a viable securities fraud claim—the Court will depart from that practice and start by describing the rules governing a motion to dismiss.

Generally, to survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). Where, as a matter of law, "the allegations in a complaint, however true, could not raise a claim of entitlement to relief," the complaint should be dismissed. *Twombly*, 550 U.S. at 558.

Securities fraud claims, however, "are subject to heightened pleading requirements that the plaintiff must meet to survive a motion to dismiss." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 321–23 (2007).

For one thing, a complaint alleging securities fraud must meet the pleading requirements of Rule 9(b), which requires plaintiffs to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *see also ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009).

For another, a securities fraud claimant must also meet the pleading requirements of the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u–4(b), which imposes a gloss on what types of complaints can be deemed "well pleaded." Under the PSLRA, a plaintiff must "specify each statement [or omission] alleged to have been misleading [and] the reason or reasons why the statement is misleading" and "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind"—*viz*, with intent "to deceive, manipulate, or defraud"—with respect to each act or omission. *Id.* "For an inference of scienter to be strong, 'a reasonable person [must] deem [it] cogent and at least as compelling as any opposing inference one could draw from the facts alleged.'" *ATSI*, 493 F.3d at 99 (quoting *Tellabs*, 551 U.S. at 324) (alteration in original).

In deciding the present motion, the Court "may consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the Securities Exchange Commission ("SEC"), and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit." *ATSI*, 493 F.3d at 98.

II. Background

The following factual allegations—which are derived from the CAC itself, items that are attached, incorporated by reference, or integral to it, Allergan's SEC filings, or from documents possessed by or known to the Plaintiff upon which it relied in bringing suit—are presumed true for present purposes.

A. The Parties

Plaintiff BRS, a pension fund, alleges that it purchased shares of Allergan at artificially inflated prices. (CAC ¶ 19.)

The Defendants include Allergan and certain of its senior executives.

Allergan is a global pharmaceutical company engaged in the development, manufacturing, and distribution of branded pharmaceutical and medical-aesthetics products. (*Id.* ¶ 32.) The Company is incorporated in Ireland, has its administrative headquarters in Parsippany, New Jersey, and is publicly traded on the New York Stock Exchange. (*Id.* ¶¶ 21, 34.)

For over thirty years, Allergan and its predecessors—specifically, McGhan Medical Corporation ("McGhan"), which later changed its name to Inamed Corporation ("Inamed") before Allergan purchased substantially all of the company in March 2006—have manufactured and sold breast implants for post-mastectomy reconstructive surgery and cosmetic augmentation. (*Id.* ¶¶ 2, 33.) Two of Allergan's breast implant product lines—the "Natrelle 410" and "Biocell"—are the subject of this lawsuit. (*Id.* ¶ 2, 7.)

The Executive Defendants include Brenton L. Saunders, Allergan's current chairman, president, and chief executive officer ("CEO") (*id.* ¶ 21); Maria Teresa Hilado, who served as Allergan's chief financial officer ("CFO") from December 2014 until February 2018 (*id.* ¶ 22);

Matthew W. Walsh, Allergan's current executive vice president and CFO (*id.* ¶ 23); Frances DeSena, who currently serves as vice president of Allergan's U.S. Brand and Research and Development Communication division (*id.* ¶ 24); Mark Marmur, a vice president in Allergan's International Communications and Press Relations division (*id.* ¶ 25); Paul Bisaro, who previously served as a director on Allergan's board of directors (*id.* ¶ 26); and William Meury, Allergan's current chief commercial officer ("CCO") (*id.* ¶ 27).

B. Summary of Applicable FDA Regulations

Before turning to the specific allegations in this case, a brief overview of how breast implant products are regulated in the United States is in order.

In the United States, breast implants are considered "medical devices," which are regulated by the FDA under the Medical Device Amendments ("MDA") of 1976, 21 U.S.C. § 301 *et seq.*, to the Federal Food, Drug, and Cosmetics Act of 1938.

The FDA categorizes medical devices into one of three regulatory classes—Class I, Class II, or Class III—based on the level of risk they pose as well as the control needed to reasonably assure their safety and effectiveness. *See id.* § 360c(a). Devices that present potentially the most "unreasonable" risk of illness or injury, are directed at "supporting or sustaining human life," or are "for a use which is of substantial importance in preventing impairment of human health," qualify as Class III devices, meaning they are subject to the highest level of regulatory scrutiny. *Id.* § 360c(a)(1)(C).

A few features of that regulatory scrutiny bear summarizing.

1. Premarket Approval

Class III devices generally must receive premarket approval from the FDA before being marketed to the public. *See id.* § 360e(a). To win premarket approval, the manufacturer of a

Class III device must provide the FDA with a "reasonable assurance" that the device is both safe and effective. *Id.* § 360e(c)(1)–360e(d)(2). To do so, a manufacturer "must submit a detailed [premarket approval] application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 109 (2d Cir. 2006) (citing 21 U.S.C. § 360e(c)), *aff'd*, 552 U.S. 312 (2008).

The FDA may condition a premarket "approval order" on a manufacturer's meeting certain post-approval conditions. *See* 21 U.S.C. §§ 360c–360j; 21 C.F.R. §§ 814.80, 814.82.

Even after issuing a premarket approval order, the FDA *can* withdraw that order based upon learning new, relevant information, and it *must* withdraw its approval if it determines that a device is unsafe or ineffective under the conditions in its labeling. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319–20 (2008) (citing 21 U.S.C. § 360e(e)(1)).

2. Reporting Obligations

After receiving premarket approval, Class III devices are subject to certain Medical Device Reporting ("MDR") requirements. 21 U.S.C. § 360i(a)(1); 21 C.F.R. § 803.50(a). Most significantly, manufacturers must file adverse event reports ("AERs") documenting when they learn that any of their devices may have caused or contributed to, or is likely to cause or contribute to, a death or serious injury. 21 C.F.R. §§ 803.10, 803.50. These AERs are publicly available through an online database called Manufacture and User Facility Device Experience

("MAUDE"). *See* U.S. FDA, MAUDE — Manufacturer and User Facility Device Experience, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

In addition to submitting AERs, Class III device manufacturers also must submit periodic reports informing the FDA of new clinical investigations or scientific studies that relate to their medical devices—both those that are known and "reasonably should be known to the applicant." *Id.* § 814.84(b)(2).

3. Complaint Procedures

Finally, manufacturers must "establish and maintain procedures for receiving, reviewing, and evaluating complaints," which includes reviewing, evaluating and investigating "[a]ny complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications" "to determine whether the complaint represents an event which is required to be reported to the FDA." *Id.* § 820.198.

C. Breast Implant Industry and Allergan's Product Launch in United States

There are three general types of breast-implant products, each defined by their filler material: saline solution, silicone gel, and composite filler. (CAC ¶ 49.) Silicone gel-filled breast implants, the particular implants at issue in this case, contain a silicone outer shell that is either smooth or textured. (*Id.*)

The history of the breast implant industry is a troubled one.

Silicone gel-filled breast implants were first introduced to the United States in 1962. (*Id.* ¶ 50.) The FDA initially classified breast implants as Class II devices. (*Id.*) However, in the early 1980s, thousands of individuals raised concerns about possible links between breast implants and numerous diseases, including autoimmune disease, cancer, connective tissue

disease, and adjuvant disease, which caused the FDA to reclassify breast implants as Class III devices. (*Id.* ¶ 51–52.)

Those concerns about the safety of breast implants did not abate. In the face of popular opinion and congressional scrutiny that implant companies were concealing evidence of dangerousness, in 1992, the FDA imposed a "voluntary mortarium" on breast implants, thereby suspending all sales and installations of devices, and required all manufacturers to submit better data ensuring the safety and efficacy of their products. (*Id.* ¶¶ 53–54.)

In 1999, a panel of independent experts at the Institute of Medicine published a review of existing studies of silicone breast implants. (*Id.* ¶ 55.) The panel concluded that, while implants caused frequent local complications, more serious problems like autoimmune disease, cancer, and other systemic illnesses were "no more common in women with breast implants than in women without implants." (*Id.*) This prompted breast-implant manufacturers and plastic surgeons to engage in a years-long, systematic lobbying campaign in an effort to reassure the public about the safety of breast implants and persuade the FDA to restore silicone breast implants to the market. (*Id.* ¶ 56.)

Ultimately and after much debate, the FDA relented: In November 2006, it approved two silicone-filled breast implants for sale in the United States. (*Id.* ¶¶ 57–60.) Its approval, however, was conditional, and the manufacturers who received approval were required to conduct six post-market safety studies, including device-failure studies, focus groups, and physician surveys assessing long term outcomes for patients with gel-filled breast implants. (*Id.* ¶¶ 60–61.) The FDA's approval letter warned, "Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a [premarket approval]." (*Id.* ¶ 62.)

One of the products approved for sale was Allergan's Natrelle product (*id.* ¶ 60)—which set in motion the allegations of fraud that follow.

D. ALCL and Allergan's Breast Implants

1. Growing Evidence of BIA-ALCL

This case concerns breast implant-associated anaplastic large-cell lymphoma ("BIA-ALCL"), which is a rare form of non-Hodgkin's lymphoma (a cancer of the immune system) that has occurred in some women with breast implants. (*Id.* ¶¶ 3, 7, 92.) BIA-ALCL typically occurs in the scar tissue surrounding the implant. (*See id.* ¶ 111.)

The first case of BIA-ALCL was reported in 1997. (*Id.* ¶ 64 (citing 1997 study).) Since then, there have been more than fifteen medical studies and regulatory alerts examining the progression of BIA-ALCL-related knowledge. (*Id.* ¶¶ 63–117.)

i. 2008-2014

In November 2008, a group of Dutch researchers conducted a study in which they identified eleven individuals with breast implants who had been diagnosed with ALCL between 1990 and 2006. (*Id.* ¶ 65.) The study found a positive association between breast implants and ALCL, with an odds ratio of 18:2—meaning that patients with implants were 18 times more likely to develop ALCL than patients without breast implants. (*Id.* (citing study).)

In January 2011, the FDA issued a report titled "Anaplastic Large Cell Lymphoma (ALCL) in Women with Breast Implants." (*Id.* ¶ 66 (citing report).) This report "review[ed the] scientific literature published form January 1997 through May 2010" and "identified 34 unique cases of ALCL." (*Id.*) The FDA stated that it "believes that there is a *possible* association between breast implants and ALCL[,]" especially as it relates to "breast implants having a textured outer shell rather than a smooth outer shell." (*Id.* (quoting report) (emphasis added).)

A month later, the United Kingdom's Medical and Health Products Regulatory Agency ("MHRA") issued a "Medical Device Alert," reporting that, "[t]here is *uncertain evidence* that women with breast implants may have a small but increased risk of anaplastic cell lymphoma (ALCL) of the breast," and encouraged "all surgeons to report all adverse incidents[,] including cases of ALCL." (*Id.* ¶ 67 (quoting report) (emphasis added).)

In response to the growing concern over BIA-ALCL, Allergan published a study in May 2012, which estimated that BIA-ALCL was linked to 1.46 out of every 100,000 breast implants. (*Id.* ¶ 71 (citing study).) Some criticized the study—which itself emphasized that its findings were "crude" and "underscore[ed] the need for definitive research"— as relying on too small a sample size and playing down the risk associated with the company's breast implants. (*Id.* ¶ 72.)

ii. 2014-2016

In the ensuing years, studies examining a possible link between ALCL and breast implants—particularly textured breast implants—mounted.

In May 2014, the European Commission and non-food Scientific Committee on Emerging and Newly Identified Health Risks ("SCENIHR") published a report identifying 130 cases of patients with poly implant prothèse breast implants who had developed ALCL. (*Id.* ¶ 73.) The MHRA then issued a second "Medical Device Alert" encouraging doctors to report cases of ALCL in women who have breast implants or have had them removed. (*Id.* (citing alert).)

In March 2015, a team of doctors published a new study identifying additional cases of BIA-ALCL—all of which were associated with textured implants, and the majority of which involved Allergan's Biocell product. (*Id.* ¶ 75 (citing study).) Two significant announcements by governmental organizations followed.

The first came later that month. The French National Cancer Institute (Agence Nationale de Sécurité du Médicament, or "ANSM") announced, "There is a clearly established link between the occurrence of this disease and the presence of a breast implant." (*Id.* ¶ 77.) It qualified this seemingly emphatic statement by "emphasi[zing] that the frequency of this complication is, however, very low[,]" and by acknowledging that the data showing the frequency of ALCL was "too low to formally identify other risk factors associated with the occurrence of this disease," was "subject to many biases," and suffered from other "missing data." (Decl. of Anna F. Connolly in Supp. Mot to Dismiss ("Connolly Decl.") Ex. 10 at 3, dated May 24, 2019, Dkt. No. 73 (cited in CAC ¶ 77).) "Nevertheless, given the data presented, the group of experts judges that it is necessary to explore the *potential association* between macrotexturing of the implant and the occurrence of BIA-ALCL." (*Id.* (emphasis added).)

The second significant announcement came more than a year later. On May 19, 2016, the World Health Organization issued a guidance document recognizing BIA-ALCL as a possible new lymphoma. (CAC ¶ 79.) It cautioned, "[A] number of studies in recent years have identified a unique form of ALK$^-$ALCL arising in association with breast implants designated as [BIA-ALCL]." (Connolly Decl. Ex. 12 at 2384 (cited in CAC ¶¶ 6, 79, 122 & n.20).) However, it too concluded, "The factors leading to progression have not been delineated." (*Id.*)

As publications warning of a link between ALCL and breast implants increased, some foreign regulators took action. In July 2016, France's ANSM released an update calling for all implant manufacturers selling in France to submit clear data for textured implants within the year, or else their respective devices could not be sold. (CAC ¶ 80 (citing update).) And Australia's Therapeutic Goods Administration ("TGA") convened an expert advisory panel to

discuss the association between breast implants and ALCL, particularly among textured implants. (*Id.* ¶ 81.)

iii. 2017

In January 2017, a group of doctors published an Allergan-sponsored study examining the incidence of capsular contracture, malposition, and late seroma[1] in patients who received the Company's Natrelle 410 breast implant. (*Id.* ¶ 87 (citing study).) While the study did not examine the incidence of BIA-ALCL, the authors noted, "Interest in late seroma has increased because of its similar clinical presentation compared with breast-implant associated large cell lymphoma. Most cases have been observed in subjects receiving textured implants." (*Id.*) Of the 17,656 patients who were studied, four developed ALCL. (*Id.*) The report concluded, "These data reaffirm the safety of the Natrelle 410 breast implant." (*Id.*)

In March 2017, the FDA released a safety communication updating the public about its current understanding of ALCL, saying, "At this time, most data suggest that BIA-ALCL occurs following implantation of breast implants with textured surfaces rather those with smooth surfaces." (*Id.* ¶ 88 (citing update).)

In April and May, two doctors from M.D. Anderson Cancer Center in Houston, Dr. Roberto Miranda and Dr. Mark W. Clemens, published two separate studies in which they found that, among other things, a plurality (or, in some cases, a majority, depending upon which database they surveyed) of cases of BIA-ALCL worldwide involved Allergan's textured implants. (*Id.* ¶¶ 91–92 (citing studies).)

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[1] Capsular contracture is the formation of scar tissue around an implant. Malposition refers to when an implant is not properly positioned behind the breast. Late seroma is a complication that manifests itself as fluid collection in the periprosthetic space.

Also in May, the *New York Times* published an article titled "A Shocking Diagnosis: Breast Implants 'Gave Me Cancer.'" (*See also* Denise Grady, *A Shocking Diagnosis: Breast Implants 'Gave Me Cancer'*, N.Y. Times (May 14, 2017), https://www.nytimes.com/2017/05/14/health/breast-implants-cancer.html (cited in CAC ¶ 93).) The article summarized the existing medical literature examining the link between ALCL and breast implants (and specifically textured breast implants), and quoted women who complained that they had not been warned about the cancer risk that their breast implants posed. (*Id.*) The article specifically observed that Allergan's implants "seem to be associated with more cases than other types, possibly because they are more deeply textured and have more surface area to stick to." (*Id.*; *see also see* Katie Forster, *Calls to Ban Textured Breast Implants After Two Die and 23 Develop Same Type of Cancer*, Independent.co.uk (Jul. 10, 2017) https://www.independent.co.uk/news/health/breast-implants-cancer-ban-two-die-23-develop-same-type-textured-common-women-enlargement-cosmetic-a7832996.html (cited in CAC ¶ 98) (similar news article documenting experts' growing concern with textured breast implants).)

Later that year, the TGA and FDA issued their own regulatory alerts, reporting that they had confirmed more cases of BIA-ALCL. (CAC ¶ 99.) Two more scientific studies examining BIA-ALCL followed (*id.* ¶¶ 100–102), one of which estimated that Biocell textured implants posed a significantly higher risk than did a leading competitor's product (*id.* ¶ 101).

iv. 2018

2018 was similar to 2017: more research, more regulatory alerts, and more news articles.

For instance, the same group of Dutch researchers who performed the first relative risk estimate for BIA-ALCL in 2008 updated their study to include all known cases of the disease from 1990 to 2016. (*Id.* ¶ 103.) They also discovered that, of the twenty-eight total patients they

surveyed whose breast implant types were known, twenty-three had macrotextured implants, all but one were made by Allergan or its predecessors. (*Id.*; *see also id.* ¶¶ 112, 114 (additional studies from September and October 2018 linking ALCL to textured implants); *id.* ¶ 117 (data presented at American Society of Hematology annual meeting linking ALCL to textured implants).)

The FDA issued a regulatory alert in March reporting that it had received 414 total reports of BIA-ACLC—up from 359 a year earlier. (*Id.* ¶ 104; *see also id.* ¶ 109 (second FDA report dated August 2018).) Australia's TGA and the United Kingdom's MHRA issued similar reports later that year. (*Id.* ¶¶ 106, 108.)

In terms of media scrutiny, the *Philadelphia Inquirer* and *ABC News* each published their own exposés that year, reporting on doctors' and patients' growing concerns about the links between breast implants (specifically textured ones) and ALCL. (*Id.* ¶¶ 110, 15.)

In August, Allergan sponsored a study to examine the tissue response associated with twelve different types of implants by different manufacturers, including Allergan's Biocell textured implant. (*Id.* ¶ 111 (citing study).) Although the researchers did not specifically study ALCL, they did note that implant surface texture plays a role in host tissue response, and that increasing the complexity of the surface texture of implants can lead to more tissue ingrowth. (*Id.*)

The next month, the Company collaborated with the FDA and other breast implant manufacturers to launch the National Breast Implant Registry ("NBIR"), a database that collects information on breast implant procedures and devices, in an effort to strengthen national oversight of breast implant devices in the United States. (*Id.* ¶ 113.)

2. Product Recall

On December 14, 2018, "GMED," the European regulatory body responsible for certifying the manufacture of medical devices in Europe, opted not to certify Allergan's breast implant portfolio, which was set to expire. (*See* Connolly Decl. Ex. 24 (ANSM information notice); *id.* Ex. 26 (Allergan's FAQ regarding CE mark non-renewal).) Four days later, France's ANSM—noting GMED's non-renewal of Allergan's "CE Mark"—asked Allergan to recall its textured breast implants. (*Id.* Ex. 24; *see also* CAC ¶¶ 11, 164.) Allergan complied the next day. (CAC ¶ 11.) It also released a statement in which it expressed its "disagree[ment]" with ANSM's decision, noting that "this action[] is not based on any new scientific evidence regarding these products." (Connolly Decl. Ex. 25.)

This lawsuit followed almost immediately. (*See* Dkt. No. 1.)

After Plaintiff filed the CAC, the FDA and Health Canada, Canada's regulator of health products, each asked Allergan to recall its Biocell breast implant products. (*See* Dkt. No. 80 (letter from counsel enclosing FDA's recall request); *see also* Health Canada, *Health Canada suspends Allergan's licenses for its Biocell breast implants after safety review concludes an increased risk of cancer* (May 28, 2019), https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/70045a-eng.php ("Health Canada Recall").) Allergan complied with those requests as well. (*Id.*)[2]

E. Allergan's Public Disclosures

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[2] The court can take judicial notice of adjudicative facts contained on government websites, because that information "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *Schwartz v. U.S. Drug Enforcement Admin.*, No. 16-750-CV, 2017 WL 2451976, at *1 (2d Cir. June 6, 2017) (summary order) (citing Fed. R. Evid. 201).

Both prior to and during the class period—which runs from January 30, 2017 through December 19, 2018 (hereinafter referred to as the "Class Period")—Defendants made various public statements concerning (*i*) the quality and safety of their breast implant products, including as it relates to ALCL; (*ii*) Allergan's compliance with applicable regulatory requirements; and (*iii*) the Company's commitment to advancing the knowledge of ALCL.

1. Defendants' Public Statements Regarding Quality and Safety of Allergan's Breast Implants

i. Statements Prior to the Class Period

Since 2011, Allergan has warned, in each of its annual SEC reports, of a "possible association" between ALCL and breast implants. (Connolly Decl. Exs. 2, 3, 5, 6, 9, 11 (Allergan's annual reports for fiscal years 2010–2015).) The Company further warned, in all but one of those filings, that "negative publicity—whether accurate or inaccurate—about the efficacy, safety or side effects of our products or product categories," could, among other things, "result in product withdrawals" and "product liability claims," which in turn "might result in" "restrictions on product use or sales[.]" (*Id.* Ex. 3 at 24; *id.* Ex. 5 at 25; *id.* Ex. 6 at 25; *id.* Ex. 9 at 27; *id.* Ex. 11 at 34 (annual report for 2011–2015 fiscal years).)

At no time did Allergan publicly assert that there was no possible association between ALCL and breast implants.

ii. Statements During the Class Period

a. Quality of Allergan's Products

In the "Overview" section of the Company's 2017 annual report, Allergan described itself as "market[ing] a portfolio of leading brands and best-in-class products for," among other things, "medical aesthetics." Allergan Plc., Annual Report (Form 10-K), at 4 (Feb. 16, 2018).

Defendants' public statements concerning the quality of the Company's breast implant products comports with that disclosure.

For example, on the Company's 2016 fourth quarter fiscal year 2016 earnings call on February 8, 2017, Saunders (Allergan's CEO and chairman) described Allergan's breast implant business as "robust." (CAC ¶ 128.) Meury (Allergan's CCO) gave an identical comment five days later, describing the Company as "number one in breast implants" and its breast implant products as "very strong[.]" (*Id.* ¶ 130.) The next month, Saunders reiterated that the Company "became the Number 1 player in breast implants last year, just slightly ahead of J&J and Mentor." (*Id.* ¶ 138.)

Defendants made similar comments as the Class Period went on. On September 7, 2017, Saunders stated that Allergan's "breast [implant] business . . . is doing incredibly well." (*Id.* ¶ 142.) Meury told investors on a 2017 third quarter earning call that the Company's "breast implants business [] had a strong quarter." (*Id.* ¶ 144.) And Saunders told attendees at the Barclays Global Healthcare Conference on March 14, 2018 that Allergan "ha[s] arguably the best products in each category of medical aesthetics," including "breast implants[.]" (*Id.* ¶ 155.)

b. Safety of Allergan's Products

In addition to touting the quality of the Company's products, Defendants also commented—in their periodic SEC disclosures, in publicly-available AERs, and in press releases—about the safety of their breast implant products, particularly as is related to ALCL.

Allergan's annual reports during the Class Period contained the exact same disclosure that appeared in the Company's previous five annual reports. It warned:

> **From time to time reports related to the quality and safety of breast implant devices are published, including reports that have suggested a possible association between anaplastic large cell lymphoma and breast implants, as well as negative reports**

> **from regulatory authorities in Europe related to a breast implant manufacturer that is not affiliated with the Company**. In addition, government investigations related to the use of products, but not the efficacy themselves, may cause reputational harm to the Company. **Negative publicity**—whether accurate or inaccurate—about the efficacy, safety or side effects of our products or product categories, whether involving us or a competitor, **could** materially reduce market acceptance to our products, cause consumers to seek alternatives to our products, **result in product withdrawals** and cause our stock price to decline. Negative publicity could also result in an **increased number of product liability claims**, whether or not these claims have a basis in scientific fact. **Any such claims**, proceedings, investigations or litigation, regardless of the merits, **might result in** substantial costs, **restrictions on product use or sales**, or otherwise injure our business.

(Connolly Decl. Ex. 14 at 29 (2016 annual report); *id.* Ex 20 at 29 (2017 annual report); Ex. 29 at 28 (2018 annual report) (emphases added).)

On May 17, 2018, Allergan submitted an AER to the FDA, which is publicly available on MAUDE, reporting a possible association between ALCL and breast implants—including Allergan's own products. The report warns:

> Based on information reported to [FDA] and found in medical literature, a possible association has been identified between breast implants and the rare development of anaplastic large cell lymphoma (alcl), a type of non-hodgkin['s] lymphoma. Women with breast implants may have a very small but increased risk of developing alcl in the fluid or scar capsule adjacent to the implant. Alcl has been reported globally in patients with an implant history that includes Allergan[']s and other manufacturers['] breast implants.

(*Id.* Ex. 4 at 1 (cited in CAC ¶ 121 & n.45).)

In addition to making formal filings with government entities, Allergan also released two additional statements in response to media inquiries about ALCL during the Class Period.

The first came in response to an *ABC News 7* article tilted "Woman who beat cancer once says breast implants caused cancer again," which was published on the first day of the Class Period (January 30, 2017). (*Id.* ¶ 83 (citing article).) The article described two women who received Allergan textured implants and participated in the Company's FDA-required post-

approval studies for two years. (*Id.*) As noted in the article, those post-approval clinical studies were scheduled to last for ten years, but, in 2014, Allergan asked to discontinue the studies after just four years—a request that the FDA granted. (*Id.*) Asked to comment on the content of the article, Allergan furnished a statement, which reads in part:

> Patient safety is always Allergan's first priority. However rare, Allergan takes [ALCL] seriously. According to the FDA, *BIA-ALCL has been reported in patients with textured breast implants from all manufacturers*. Because of the limited number of confirmed BIA-ALCL case[s] worldwide, the medical community has not been able to establish causality.

(Connolly Decl. Ex. 13 (*ABC News 7* article) (cited in CAC ¶¶ 8–9, 83–86, 125–26 & n.23) (emphasis added).)

The second Allergan statement came four months later. On May 29, 2018, Allergan issued a press release titled "Allergan Responds to Media Reports on Breast Implant Associated Anaplastic Cell Lymphoma (BIA-ALCL)." Almost everything in that statement is pertinent to the present motion, so it must be reproduced here in its entirety:

> Safety Profile of Allergan Breast Implants
>
> Allergan manufactures a broad portfolio of breast implants, including those with textured and smooth surfaces. **To date, we are not aware of any BIA-ALCL cases that have been found with other Allergan implants in Australia and New Zealand that do not include Biocell.** Plastic Surgeons and patients have a variety of reasons for selecting a textured implant, and patients are advised to have a thorough discussion with their plastic surgeon about the risks and benefits of each implant type to make an informed decision.
>
> **The safety profile of Allergan's smooth and textured breast implants is supported by extensive pre-clinical device testing, more than a decade of U.S. and European clinical experience involving more than 160,000 women, as well as a large number of peer-reviewed and published studies.**
>
> Allergan's Global Breast Implant Warranty
>
> On April 1st, 2018 Allergan became the first implant manufacturer to add the rare events of BIA-ALCL and capsular contracture Baker Grade III/IV to their global breast implant warranty. The warranty provides out-of-pocket surgical cost assistance toward the

removal of the breast implant(s) and the associated scar tissue (complete capsulectomy). Allergan will also provide replacement implant(s) at no charge.

Regulatory Reviews of BIA-ALCL

In response to recent media reports of breast implants and BIA-ALCL, it is important for patients and physicians to understand the facts around the benefits and risks of breast implants.

Over the past 15 years, there has been scientific discussion about cases of ALCL being reported very rarely in women who have also had breast implant procedures. The national health regulator in the UK (the Medicines & Healthcare Products Regulatory Agency or MHRA),[3] the French regulator (Agence Nationale de Sécurité du Médicament et des Produits de Santé or ANSM), the U.S. regulatory authority (the Food and Drug Administration or FDA), and Australia's Therapeutic Goods Administration (TGA) have continuously evaluated these case reports and acknowledge that the cases of BIA-ALCL represent a very low occurrence in the estimated 5-10 million women around the world who have had breast implant procedures.

Based on all of the available scientific information, the MHRA, the ANSM, the U.S. FDA and the TGA are not recommending any change in current best practice to post-implant care and check-ups. Women with breast implants should be advised to perform regular breast self-examination and consult their healthcare provider if they notice changes. Patients should talk with their healthcare provider for medical guidance, if concerned. Physicians are reminded that any suspected cases should be referred to an appropriate specialist for evaluation and treatment.

. . .

When diagnosed and treated early by a surgical specialist, BIA-ALCL has a good prognosis. Worldwide, **BIA-ALCL has been reported with multiple different implant manufacturers. Direct causality has not been established with implants from a specific manufacturer**. . . .

(Connolly Decl. Ex. 21 (cited in CAC ¶ 107) (emphases added).)

2. Defendants' Public Statements Regarding the Extent to Which Allergan Complies with Applicable Regulation and Shares Information with the FDA

During the Class Period, Allergan represented that it had complied with its regulatory obligations.

In response to the January 30, 2017 *ABC News 7* article reporting that the FDA granted Allergan's request to discontinue its post-approval studies, DeSena (Allergan's vice president of U.S. Brand Research and Development Communication division) stated, "Allergan complied with standard protocols and regulations relating to the termination of studies, which included proper notification to the trial sites and in the Institutional Review Boards." (CAC ¶ 83.) She further asserted:

> Allergan continues to provide educational information regarding this disease to both physicians and patients, as well as working with the FDA and regulatory authorities to collect and assess safety reports to help inform the physician community, regulatory agencies and patients on the appropriate use of our implants. . . .
>
> **Allergan complies with applicable regulations relating to the reporting of BIA-ALCL to the FDA**. The FDA has a webpage devoted to reports of ALCL it receives from breast implant manufacturers, which includes the date range of the reports, information regarding the type of implants, whether the surgery was for reconstruction or augmentation, etc.

(*Id.* ¶ 86 (emphasis added).)

Allergan's 2016 and 2017 annual reports similarly reference the Company's adherence to its regulatory requirements:

> Our medical device product candidates, including our breast implants, must undergo rigorous clinical testing and an extensive government regulatory clearance or approval process prior to sale in the United States and other countries. . . . Approved products and their manufacturers are subject to ongoing review, and discovery of previously unknown problems with products may result in restrictions on their manufacture, sale, use or their withdrawal from the market.

Allergan Plc., Annual Report (Form 10-K), at 18 (Feb. 16, 2018); Allergan Plc., Annual Report (Form 10-K), at 18 (Feb. 24, 2017).

After Allergan's voluntary product recall, Allergan reiterated that it is "committed to strict adherence to all regulatory requirements, to the most rigorous scientific evidence and to highest industry standards for [its] products." (Connolly Decl. Ex. 25.)

3. Defendants' Public Statements Concerning Allergan's Efforts to Advance BIA-ALCL Knowledge

Responding to various media inquiries, Defendants represented during the Class Period that they were committed to supporting the study of BIA-ALCL.

For instance, in the January 30, 2017 *ABC News 7* article, Desena—asked to explain why Allergan stopped conducting additional post-approval studies—stated that "Allergan fulfilled all of its post-approval commitments in 2014 and requested FDA's approval to discontinue the studies early in light of Allergan meeting all post-approval commitments. FDA approved Allergan's request[,] and the studies were discontinued in 2014. The discontinuation of these post-approval studies had nothing to do with BIA-ALCL." (CAC ¶ 83.)

She reiterated later in the article that "Allergan has a robust post-market surveillance process"—including "collecting reports of BIA-ALCL from surgeons, notifying FDA and other international regulatory agencies of all suspected cases, [and] monitoring literature and case presentations"—"to monitor and report suspected cases of BIA-ALCL." (*Id.*) "Allergan continues to provide educational information regarding this disease to both physicians and patients, as well as working with the FDA and regulatory authorities to collect and assess safety reports." (*Id.* ¶ 86.)

Marmur (an associate vice president in Allergan's International Communications and Press Release division) added that, "Allergan is actively working to help advance the knowledge of this disease, understand the association of BIA-ALCLC and textured implants, and educate the community, including" by "working closely with the FDA and global regulatory bodies[,]" "convening global medical experts and researchers[,]" and "supporting ongoing research[.]" (*Id.* ¶ 84.)

Similar statements were provided in response to other media inquiries as well.

Commenting on the *New York Time*'s May 14, 2017 article reporting on BIA-ALCL, an Allergan spokesman stated that Company was "studying bacterial biofilms[] and immune and inflammatory responses to breast implants," "[takes] the disease seriously[,] and [is] working with professional societies to distribute educational materials about it." (*Id.* ¶ 94.)[3]

Responding to another *New York Times* article on March 21, 2018, Marmur purportedly told the reporter by email that the Company "was paying for research by outside investigators into causes of lymphoma, working with plastic surgery societies on improved surgical techniques, adding information about the disease to its labeling and website, and giving surgeons educational materials for patients." (*Id.* ¶ 105 (citing article[4]).)

And in response to an *ABC News* article dated November 26, 2018, an Allergan spokesperson reiterated that the Company "is and has been fully committed to investing in and supporting work to further understanding and increasing awareness of breast implant-associated ALCL." (*Id.* ¶ 162.)

F. Allegations of Fraud

On March 21, 2019, the Court appointed BRS to serve as Lead Plaintiff. (Dkt. No. 49.) It filed the CAC, the operative complaint in this action, a month later. (Dkt. No. 58.) In that pleading, Plaintiff asserts claims for securities fraud, pursuant to Section 10(b) of the Exchange

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[3] This remark was not placed in quotation marks in the article; rather, the *Times* paraphrased Allergan's response. Accordingly, the Court places Allergan's purported response in quotation marks here only to denote how they appear in the *Times* article.

[4] Here, too, the *Times* reporter paraphrased Allergan's response rather than quoting from it directly, making it impossible to know the exact language Defendants used.

Act and Rule 10b-5 promulgated thereunder, against all Defendants (Count I), and control person liability under Section 20(a) of the Exchange Act against the Executive Defendants (Count II). In essence, the CAC alleges that Defendants (*i*) unlawfully omitted to state that there was a "definitive" link between ALCL and breast implants, particularly textured ones; (*ii*) misrepresented the extent to which they complied with Allergan's regulatory obligations; and (*iii*) falsely stated that the Company was studying a possible connection between ALCL and breast implants while working to undermine such efforts.

1. Failed to Disclose a "Definitive" Link Between ALCL and Breast Implants

i. Alleged Fraud

Plaintiff alleges that Defendants' statements concerning the quality and safety of Allergan's breast implant products were misleading because they omitted to state that there was a "definitive" link between ALCL and Allergan's breast implants—a link that purportedly was established by the various research articles and regulatory alerts identified above, *supra* at II(D)(1). (CAC ¶¶ 127, 129, 131, 137, 139, 141, 143, 145, 147, 154, 156, 158, 161, 163.) This allegation takes a few forms. Some are supported by additional allegations in the CAC; others are grounded purely in legal argument.

First, Plaintiff argues that Allergan's public disclosures—which acknowledges that there was a "possible" association between ALCL and breast implants—were insufficient because they were "passively phrased and boilerplate." (*See* Pl.'s Opp. to Defs.' Mot. to Dismiss ("Pl.'s Opp.") at 15, dated June 28, 2019, Dkt. No. 76.)

Second and relatedly, Plaintiff argues that Allergan's statement that "a breast implant manufacturer that is not affiliated with the Company" was the subject of "negative reports from

regulatory authorities in Europe"—a statement that appeared in every Allergan annual report for fiscal years 2011 through 2018—was misleading because Allergan failed to disclose that it too was subject to scrutiny from European regulators. (*Id.* at 10–11 (citing CAC ¶ 80).)

Third, Plaintiff pleads that Allergan has received "various consumer complaints" that the Company is not "appropriately advising patients of the risks associated with . . . BIA-ALCL." (CAC ¶¶ 10(viii), 127, 137, 141, 154, 158, 163.) While Allergan eventually added a warranty for its breast implant products in 2018, *supra* at 19, it announced that move in the same press release in which it emphasized the "safety profile" of its implants and that "BIA-ALCL has a good prognosis" (CAC ¶ 107), thereby concealing the alleged "definitive" link from the public.

Fourth, Plaintiff identifies two former Allergan employees (hereinafter referred to as the "Confidential Witnesses"), who anonymously allege that the company knew about the purported risks posed by its breast products to a greater degree than the Company publicly disclosed.

Confidential Witness 1 ("CW1"), a senior project manager for Allergan who was based at the Company's Santa Barbara from June 2010 to November 2014 (*Id.* ¶ 29), alleges that Allergan started to change the texture and manufacturing technique of its textured implants "sometime during the last year of [her] employment" (*id.* ¶ 74). "While CW1 was not told by the Company that these suggested changes were related to the link between textured implants and the development of ALCL, it was shortly thereafter that studies began to be published alerting to this precise link." (*Id.*)

Confidential Witness 2 ("CW2") was a part of a team of researchers who conducted tests and studies on the Company's products from 2010 until June 2017. (*Id.* ¶¶ 31–32.) She alleges, among other things, that she and her colleagues were "well-aware [*sic*] of the reports about the possible link [between ALCL and breast implants]," because "they heard about it" from

published research papers, media reports, and at presentations at "a number of conferences for breast implant surgeons," to which Allergan sent its "researchers and management." (*Id.* ¶ 96.) Allergan, therefore, "was well-aware [*sic*] of the link[.]" (*Id.* ¶ 97.)

2. Misrepresentations Concerning Compliance with Regulatory Requirements and Information Sharing with FDA

Plaintiff contends that Defendants' public assurances that Allergan fulfills its regulatory obligations were materially misleading because the Company allegedly did not comply with the applicable regulations governing the submission of AERs. (*See* CAC ¶¶ 127, 137, 141, 154, 163.) This allegation takes two forms.

First, Plaintiff alleges that Allergan submitted a "significant" number of AERs using an incorrect manufacturer name—"Costa Rica or "Santa Barbara," referring to its office site, instead of "Allergan"—which purportedly made it more difficult for consumers, doctors, or the FDA to notice troubling patterns in the Company's product lineup. (*Id.* ¶ 120.)

Next, until 2017, Allergan allegedly did not submit individualized AERs for each adverse event. (*Id.* ¶ 121.) Instead, it filed Alternative Summary Reports ("ASRs") to report multiple adverse events at a time. (*Id.*) Under the ASR program, manufacturers could report "well-known and well-documented [issues] with the FDA," thereby "cut[ting] down on redundant paperwork" and "allow[ing] the FDA to more efficiently review adverse events." (Connolly Decl. Ex. 3 at 7, 3 (cited in CAC ¶ 121 & n.44).) According to Plaintiff, Allergan used the ASR program—"which (1) require far less detail and (2) are not publicly available on MAUDE"—to "bury[] evidence of ruptures and other injuries by reporting them as routine events that did not require public disclosure." (CAC ¶ 121.) The FDA discontinued the ASR program in 2019. (Connolly Decl. Ex. 35; *see also* Decl. of Murielle J. Steven Walsh in Opp. Mot. to Dismiss

("Walsh Decl.") Ex. Q (FDA statement formally ending ASR program), dated June 28, 2019, Dkt. No. 77.)

3. Misrepresentations Concerning Allergan's Efforts to Study Possible Connection Between Breast Implants and ALCL

Plaintiff alleges Defendants various press statements emphasizing Allergan's commitment to supporting the study of BIA-ALCL were false because Defendants were secretly seeking to undermine, rather than support, the study of BIA-ALCL. (CAC ¶¶ 127, 137, 141, 154, 158, 163.) Specifically, it asserts that those statements cannot be squared with (*i*) Allergan's asking the FDA to prematurely terminate its obligation to conduct post-approval clinical studies of its breast implant products, and (*ii*) CW2's experiences at Allergan. According to CW2, the Company never asked its breast implant research team (of which CW2 was part) to conduct any studies into claims that breast implants were causing ALCL. (*Id.* ¶ 95.) CW2 claims that her team knew about BIA-ALCL, but "[they did not want to go there[.]" (*Id.*) To make matters worse, in 2014, Allergan "shut down its Santa Barbara facility, which was the center of breast implant research and development," laid off 25 team members, and transferred the remaining five (one of whom was CW2) to the Company's Irvine facilities. (*Id.* ¶ 97.)

III. Discussion

Defendants now move to dismiss the complaint for failure to state a claim upon which relief can be granted.

A. The Motion to Dismiss the Section 10(b) Claim is Granted in Part

Section 10(b) of the Exchange Act makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). SEC Rule 10b-5, which implements the statute, prohibits making "any untrue statement

of a material fact or [omitting] to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). To recover for a violation of Section 10(b) and Rule 10b-5, a private securities plaintiff must prove six elements: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *City of Westland Police & Fire Ret. Sys. v. MetLife, Inc.*, 129 F. Supp. 3d 48, 65 (S.D.N.Y. 2015) (quoting *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 267 (2014)).

Defendants assert that Plaintiff has failed to plausibly allege a material omission or misstatement, scienter, reliance, and loss causation. Each of those contested elements will be addressed below. As to Rule 10b-5's other elements, the Court finds that the allegations contained in the CAC suffice.

1. Material Misrepresentation or Omission

To adequately allege a material misrepresentation or omission, a plaintiff must plead facts that, if true, would be sufficient to show that the defendant either made an untrue statement of a material fact or omitted to state a material fact necessary to make whatever statements it made not misleading. 17 C.F.R. § 240.10b-5(b).

"A violation of Section 10(b) and Rule 10b-5 premised on misstatements cannot occur unless an alleged material misstatement was false *at the time it was made*." *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014), *aff'd*, 604 Fed. App'x. 62 (2d Cir. 2015) (emphasis in original) (citing *San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos., Inc.*, 75 F.3d 801, 812–13 (2d Cir. 1996)). A statement believed to be true when

made, but later shown to be false, is insufficient, because it lacks contemporaneous falsity. *Id.* (citing *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000)). "[F]alsity is a failure to be truthful—it is not a misapprehension, misunderstanding, or mistake of fact at the time a statement was made." *San Leandro,* 75 F.3d at 813. Moreover, a plaintiff "must do more than simply assert that a statement is false—[it] must demonstrate with specificity why that is so." *Lululemon*, 14 F. Supp. 3d at 571 (quoting *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004)).

Similar to the falsity of statements, omissions are only actionable if a defendant is under a duty to disclose and fails to do so. *Levitt v. J.P. Morgan Sec., Inc.*, 710 F.3d 454, 465 (2d Cir. 2013) (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988)). Such a duty to disclose arises where a "statute or regulation requir[es] disclosure" or a corporate statement would otherwise be "inaccurate, incomplete, or misleading." *Stratte–McClure v. Morgan Stanley*, 776 F.3d 94, 101 (2d Cir. 2015) (quoting *Glazer v. Formica Corp.,* 964 F.2d 149, 157 (2d Cir. 1992).

"An alleged misrepresentation is material if there is a substantial likelihood that a reasonable person would consider it important whether to buy or sell shares of stock." *Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019) (internal quotation marks and citation omitted); *accord TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976). Materiality turns on whether the statement "significantly altered the 'total mix' of information made available." *Id.* (internal quotation marks and citation omitted); *accord Basic v. Levinson*, 485 U.S. 224, 231–32 (1988).

As noted, Plaintiff alleges that Defendants made three categories of misstatements or omissions. *Supra* at II(A)(F). Each will be evaluated in turn.

i. Failure to Disclose "Definitive Link" Between ALCL and Breast Implants

a. The Existence of a "Definitive Link" Between ALCL and Allergan's Breast Implants

Plaintiff asserts that Allergan had a duty to disclose the "definitive" link between the Company's breast implant products and ALCL so as not to render false their other public statement touting the quality and safety of those products. Indeed, the phrase "definitively linked" appears countless times in the CAC. (*E.g.*, CAC ¶¶10(i), 127, 129, 131, 137, 139, 141, 143, 145, 147, 154, 156, 158, 161, 163.)

When a securities fraud action rests on the failure to disclose a given fact, the complaint must state a plausible claim that the underlying fact actually exists. *See Menaldi v. Och-Ziff Capital Mgmt. Grp. LLC*, 164 F. Supp. 3d 568, 578 (S.D.N.Y. 2016), *reconsideration denied*, No. 14 Civ. 3251, 2016 WL 2642223 (S.D.N.Y. May 6, 2016) (citing *In re Axis Capital Holdings, Ltd. Sec. Litig.*, 456 F. Supp. 2d 576, 585 (S.D.N.Y. 2006), *In re Yukos Oil Co. Secs. Litig.*, No. 04 Civ. 5243, 2006 WL 3026024, at *14 (S.D.N.Y. Oct. 25, 2006), & *In re JP Morgan Chase Secs. Litig.*, 363 F. Supp. 2d 595, 632 (S.D.N.Y. 2005)); *see also In re Mylan N.V. Sec. Litig.*, 379 F. Supp. 3d 198, 207 (S.D.N.Y. 2019).

The CAC fails to plausibly do that here. In fact, it says the opposite—that even after taking into account the latest scientific research and regulatory alerts on the matter, nothing has been "definitively" established about ALCL, because the causes of ALCL are presently unknown.

Let's start with the medical research. Of the myriad studies cited in the CAC, none speaks of a definitive link. The following examples are illustrative.

One study from March 2015 titled "Analplastic large cell lymphoma occurring in women with breast implants"—a study that Plaintiff characterized as a "major analysis" (CAC ¶ 75)—described BIA-ALCL as "a novel manifestation of site- and material-specific lymphoma originating in a specific scar location**, presenting a wide array of diverse characteristics and suggesting a multifactorial cause**" (Walsh Decl. Ex. C. at 1 (cited in CAC ¶ 75) (emphasis added).)

Another study that month, noting the "***association*** of breast implants and [ALCL]," warned that "there are still very few cases of breast implant-associated ALCL reported in the literature, **which makes identification of risk factors for . . . this disease difficult**." (*Id.* Ex. D. at 713, 19 (cited in CAC ¶ 76) (emphasis added).)

In April 2017, two physicians from M.D. Anderson Cancer Center published a study containing the following pertinent conclusions: (*i*) "**More information is needed** to fully understand risk factors and etiology [of BIA-ALCL;" (*ii*) "While theories have been postulated on the potential etiology of BIA-ALCL, **pathogenesis has not yet been clearly defined**;" and (*iii*) "A number of epidemiologic **studies have failed to show an association** between breast augmentation and risk lymphoma . . . ." (*Id.* Ex. H (cited in CAC ¶ 91) (emphases added).)

Another "explosive study" in October 2017—again, those are Plaintiff's words, not the Court's (CAC ¶ 100)—emphasized, "We believe that the genesis of breast implant-associated ALCL is thus **multifactorial**, as is the case with most carcinogenesis." (*Id.* Ex. J at 653 (cited in CAC ¶¶ 100–01) (emphasis added).)

On January 4, 2018, the Journal of the American Medical Association concluded, in no uncertain terms, that various "**considerations preclude reliable conclusions on associations**

between implant types or vendors and the risk of developing BIA-ALCL." (Connolly Decl. Ex. 19 at 9 (cited in CAC ¶ 103 & n.34).)

Further examples from throughout and even after the Class Period abound. (*See, e.g.*, Walsh Decl Ex. K at 1163 (cited in CAC ¶ 102) (December 2017 report writing, "Textured implants develop a significantly higher load of bacterial biofilm compared with smooth implants. . . . However, **this theory has not been fully substantiated as causal yet.**") (emphasis added); Connolly Decl. Ex. 27 at 30 (cited in CAC ¶ 112 & n.41) (January 2019 study concluding that "**associations need to be further analyzed with patient-level data to provide conclusive evidence**") (emphasis added); Walsh Decl. Ex. L at 177 (cited in CAC ¶ 112) (February 2019 report stating, "**The pathogenesis of breast implant ALCL is not well defined**, however, several plausible mechanisms have been proposed.") (emphasis added); *id.* Ex. M at 1 (cited in CAC ¶114) (April 2019 report stating, "Bacterial biofilms have been implicated with breast implant complications including . . . anaplastic large-cell lymphoma. **The actual mechanism[] . . . [is] still under active investigation and [is] not clear.**") (emphasis added).)

In summary, Plaintiff's assertion that Allergan's breast implants were "definitively linked" to ALCL, thereby giving rise to a duty of disclosure, is belied by the very sources on which it relies.

Nor do the repeated regulatory alerts cited in the CAC—from before, during, and after the Class Period—plausibly establish the presence of a "definitive" link.

Take, for example, this statement from the UK's MHRA, which ran in an article in the *Independent* in July 2017: "**In the UK, there is currently no definitive evidence of an association with ALCL and any specific make or model of breast implant.**" (Connolly Decl. Ex. 16 at 3 (cited in CAC ¶ 98 & n.30) (emphases added).)

Next, consider the conclusion offered by a Health Canada representative at the FDA's General Plastic Surgery Devices advisory committee meeting, which took place on March 25 and 26, 2019. Presenting on Canada's ongoing "regulatory actions and activities," the representative concluded that, after reviewing "marketing and BIA-ALCL cases for the period 2007–2016" and considering "[e]tiologic theories and risk factors," "**a definitive causal link could not be established**." (Connolly Decl. Ex. 31 at 6 (cited in CAC ¶ 174) (emphases added).)

Indeed, at that same meeting, the FDA reached a similar conclusion as Health Canada. Acknowledging that "[t]here are hypotheses that propose a link between breast implant texturing and BIA-ALCL[,]" "[a]dditional hypothesized risk factors include genetic predisposition, and chronic inflammation and biofilm formation around the breast implant." (Connolly Decl. Ex. 33 at 7 (cited in CAC ¶¶ 171–72).) "[T]he pathogenic mechanism of BIA-ALCL has not been determined[.]" (*Id.*)

Accordingly, here too, Plaintiff's assertion that a "definitive link" exists is overwhelmingly contradicted by the regulatory alerts it relies upon in the CAC.

The CAC does identify one item that, read alone, supports the notion of a "definitive link." It reads:

> In March 2015, the French National Cancer Institute (Agence Nationale de Sécurité du Médicament, "ANSM") announced, "There is a clearly established link between the occurrence of this disease and the presence of a breast implant."

(CAC ¶ 77.)

However, setting aside for the moment all other issues with this statement—that it was published more than two years before the Class Period; that every other piece of evidence cited in the complaint is to the contrary; that it addresses a link between breast implants generally rather than Allergan's textured products; that it expresses the opinion of a single entity at a

discrete point in time without any suggestion that it represented the prevailing wisdom then, let alone during the Class Period two years later—this excerpted statement is insufficient because it is qualified, if not contradicted, by the later sentences that follow:

> The published data are **subject to many biases**. Furthermore, there are **many missing data**, both from the literature and from the French cases. Nevertheless, given the data presented, the group of experts judges that it is necessary to explore the **potential association** between macrotexturing of the implant and the occurrence of BIA-ALCL.

(Connolly Decl. Ex. 10 at 3.) Plaintiff omitted this qualifying language from the CAC. Nevertheless, it renders implausible any suggestion that the ANSM report "definitively" establishes anything; it merely announces a potential association, which is not "definitive."

Based on the foregoing, Plaintiff has not plausibly alleged the existence of a "definitive link" between Allergan's implants and ALCL.

b. Defendants' Disclosures Warning of a Possible Association Between ALCL and Allergan's Breast Implants

Perhaps recognizing that its securities fraud claim is not viable as pleaded, Plaintiff argues in its opposition brief that it need only show the existence a "plausible biological link"—not a "definitive link"—between ALCL and Allergan's breast implants to state a claim for securities fraud. (Pl.'s Opp. at 17 (citing *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 46 n.13 (2011)).) Putting aside the fact that the CAC only uses the phrase "definitively linked" and says nothing about a "plausible biological link," Plaintiff's claim fails even under a "plausible biological link" standard.

Securities-fraud-by-omission assumes a failure to disclose. But Allergan's disclosures repeatedly apprised the public of the possibility of an association between ALCL and breast implants.

Allergan's annual reports during the Class Period (and before it) warned of a "possible association between anaplastic large cell lymphoma and breast implants[.]" (Connolly Decl. Exs. 14 at 29; *id.* Ex. 20 at 29; *id.* Ex. 29 at 29; *see also id.* Exs. 2, 3, 5, 6, 9, 11 (annual reports for fiscal years 2010–2015).)

Allergan's press releases during the Class Period contained similar representations, including that (*i*) "BIA-ALCL has been reported in patients with textured breast implants from all manufacturers (*id.* Ex. 13); (*ii*) "BIA-ALCL has been reported with multiple different implant manufacturers[,]" (*id.* Ex. 21); (*iii*) "[d]irect causality has not been established with implants from a specific manufacturer" (*id.*); and (*iv*) the FDA, MHRA, ANSM, and Australia's TGA "have continuously evaluated [BIA-ALCL] case reports and acknowledge that the cases of BIA-ALCL represent a very low occurrence in the estimated 5-10 million women around the world who have had breast implant procedures" (*id*).

And an AER submitted by Allergan to the FDA on May 17, 2018, which warned of "a possible association" between ALCL and breast implants "[b]ased on information reported to [the FDA] and found in medical literature," also disclosed that "ALCL has been reported globally in patients with an implant history that includes Allergan[']s . . . breast implants." (*Id.* Ex. 4 at 1.)

These disclosures, which incorporate the same language used by the medical and regulatory communities in describing BIA-ALCL, warned of a potential link between ALCL and Allergan's implants.

A few cases are instructive.

The first is the case relied upon by Plaintiff—*Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27 (2011).

In that case, the plaintiff alleged that Matrixx, a pharmaceutical company, committed securities fraud by failing to disclose reports of a possible link between its leading product, Zicam, a cold remedy, and anosmia, the loss of smell. *Matrixx*, 563 U.S. at 30. As is the case here, there were credible reports and complaints linking Zicam to anosmia, including those generated by doctors. *Id.* at 32–33. In the face of these reports, Matrixx executives declared that the company was "'poised for growth'" and had "'very strong momentum[.]'" *Id.* at 33. Critically—unlike Allergan—the company *did not disclose any potential association between Zicam and anosmia*. *Id.* at 31. Instead, it issued a generalized warning that a "'material adverse effect'" could result from product liability claims, "'whether or not proven to be valid[.]" *Id.* at 34. When media reports surfaced that the FDA was investigating Zicam, the company issued a press release flatly denying any link, stating, "Matrixx believe statements alleging intranasal Zicam products caused anosmia (loss of smell) are completely unfounded and misleading." *Id.*

On the basis of these allegations, a putative class of investors sued for securities fraud, alleging that Matrixx had a duty to disclose the possible association between Zicam and anosmia. Matrixx argued that certain of the studies that the investors relied upon did not suffice to establish a possible association because they involved testing on fish rather than humans. *Id.* at 46 n.13. The Supreme Court rejected this contention. "The existence of the studies," the Court reasoned, "suggests a plausible biological link between zinc and anosmia, which, in combination with the other allegations, is sufficient to survive a motion to dismiss." *Id.* It is this particular sentence that Plaintiff now relies upon in asserting that *Matrixx* is dispositive of the case at bar.

This case differs from *Matrixx* in one glaringly obvious respect: Whereas Matrixx affirmatively denied any possible link between Zicam and anosmia, Allergan repeatedly disclosed that there was a possible association between ALCL and breast implants, including

textured ones. *Compare id.* at 31 *with supra* II(E)(1). Had Defendants in this case failed to disclose the existence of any possible association between ALCL and breast implants, then *Matrixx* would be apposite. But they did not fail to disclose that link. So *Matrixx*—including its use of the "plausible biological link" language that Plaintiff now cherry-picks—lends very little to Plaintiff's argument.

The second case worth examining is one that both parties cite in their briefs as supporting their respective positions. In *Bettis v. Aixtron SE*, No. 16 Civ. 00025 (CM), 2016 WL 7468194, at *1 (S.D.N.Y. Dec. 20, 2016), a putative class of purchasers sued Aixtron, a technology company that manufacturers equipment for customers in the semiconductor industry, alleging that the company failed to disclose material facts that would have indicated to a reasonable investor that it likely would not fulfill a large product order.

This Court dismissed the complaint for various reasons, one of which has purchase here. I noted that "Aixtron made exactly the disclosures that Plaintiff claims were withheld from investors[.]" *Id.* at 11. In *Bettis*, Aixtron's management warned that the transaction at issue had "taken longer than we would have liked," which was "adequate to inform investors that the qualification process was still ongoing and was taking longer than anticipated." *Id.* So too, here, Plaintiff accuses Allergan of failing to disclose a possible biological link between Allergan's breast implants and ALCL even though it did exactly that—it warned of a possible association between breast implants, including its own products, and ALCL.

In reaching my conclusion in *Bettis*, I analogized the case to *Caiafa v. Sea Containers Ltd.*, 525 F. Supp. 2d 398 (S.D.N.Y. 2007), a case in which Judge Berman dismissed a Rule 10b-5 claim premised on the defendants' alleged failure to disclose that the company lacked "sufficient personnel resources and technical accounting expertise" to comply with GAAP,

when, in fact, the company repeatedly disclosed that there were internal weaknesses in the company's accounting department. *Id.* at 411. *See also In re ProShares Tr. Sec. Litig.*, 78 F.3d 96 (2d Cir. 2013) ("when a [defendant] warns of the exact risk that later materialized, a [securities] claim will not lie as a matter of law").

The third case worthy of analysis is *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 517 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016).

In that case, defendant Sanofi, a global pharmaceutical company, and its corporate officers made various public statements expressing optimism that the FDA would approve its new drug, Lemtrada. *Id.* at 531. The plaintiff alleged that these statements were misleading because they were not accompanied by any mention of certain concerns that the FDA had privately expressed to Sanofi's officers about the design of Lemtrada's clinical trials. *Id.* at 531, 535. When the FDA initially declined to approve Lemtrada, the plaintiffs sued for securities fraud.

The court dismissed the complaint. As relevant here, even though Sanofi's predecessor represented in its annual report that it "anticipate[s] product approval in the United States," *id.* at 535, it later warned:

> [A] regulatory authority may deny or delay an approval because it was not satisfied with the structure or conduct of clinical trials or due to its assessment of the data we supply. A regulatory authority, for instance, may not believe that we have adequately addressed negative safety signals. Clinical data are subject to varied interpretations, and regulatory authorities may disagree with our assessments of data.

Id. at 536 (citing predecessor's 10-K). Judge Engelmayer reasoned that this and other similar disclosures "conveyed substantive information about the risk that ultimately materialized," and, "[a]s such, they were meaningful cautionary language, not mere boilerplate" so as to insulate Sanofi from securities fraud liability. *Id.*

The same principles apply here. Allergan disclosed that breast implants, including the Company's own products, had been associated with a particular type of cancer, and that link—whether it was eventually substantiated or not—could produce a number of negative outcomes, including bad publicity, product liability claims, and, as pertinent here, "product withdrawals"—all risks that could "cause [Allergan's] stock price to decline." (Connolly Decl. Exs. 14, 20, 29.) Those negative outcomes materialized, culminating in the recall of Allergan's implants from the North American and European markets. But Allergan's initial disclosures were not false or fraudulent—the fact that these things eventually happened means that they were true.

To the extent Plaintiff asserts that Allergan was insufficiently specific in warning that a product recall would materialize, it is black letter law that a company is not obligated to take the gloomiest view of its business. *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129 (2d Cir. 1994); *Novak*, 216 F.3d at 309. The CAC does not plead any facts, let alone particularized ones, that Allergan knew that a recall was in the works, so it cannot be held liable for not publicly predicting that risk.

Moreover, as suggested in the ANSM statement announcing Allergan's product recall, that recall was not based on the identification of a causal link between ALCL and Allergan's breast implants. "*The ANSM has not yet identified any immediate health risk to women carrying the implants concerned*," the recall notice states, but that "pending the opinion of a committee of experts," it "recommended [that] health professions [] use implants with a smooth envelope[.]" (*See* Connolly Decl. Ex. 24 at 1 (emphasis added).) Put otherwise, the regulators concluded that would be safer, all things considered, to take Allergan's implants off the market until a causal link was either established or disproven. If uncertainty is the reason for the recall—and the CAC

does not plausibly allege otherwise—then there is no plausible claim for the failure to disclose that risk, because Allergan made sure that the investing public knew about that very possibility.

c. Plaintiff's Remaining Contentions Concerning Defendants' Statements About the Quality and Safety of Allergan's Breast Implants

Having concluded that the CAC fails to plausibly allege a "definitive" link between ALCL and Allergan's breast implants, the Court now turns to Plaintiff's remaining contentions that certain of Defendants' affirmative statements were misleadingly incomplete.

First, Plaintiff alleges that Allergan received "various consumer complaints" that the Company was not "appropriately advising patients of the risks associated with . . . BIA-ALCL." (CAC ¶¶ 10(viii), 127, 137, 141, 154, 158, 164.) Nowhere does the CAC cite these complaints, much less provide details about what they allege or whether they adequately show patients were not appropriately advised of any risks during the relevant time period. Nor does the CAC identify any particular statement by Defendants that would be rendered false by this allegation. Indeed, Plaintiff's does not even attempt to defend this particular allegation in its opposition brief.

Second, Plaintiff asserts that Defendants' various statements about the quality of Allergan's breast implant business—*e.g.*, Allergan is "number one in breast implants," possesses a "very strong product line," is "doing incredibly well," and the like, *supra* at II(E)(1)(ii)(a)—were misleadingly incomplete for failing to disclose the "definitive" link between the Company's breast implants and ALCL. These statements constitute textbook examples of puffery, as they are too generalized and aspirational for an investor to take them seriously. *City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 183 (2d Cir. 2014). As recognized in *In re Gentiva Sec. Litig.*, 932 F. Supp. 2d 352 (E.D.N.Y. 2013), general descriptors like

"robust" or "best in class" "fall 'into the category of commonplace statements too general to cause reliance by a reasonable investor.'" *Id.* at 370 (quoting *In re Wachovia Equity Sec. Litig.*, 753 F. Supp. 2d 326, 354 (S.D.N.Y. 2011)).

Third, Plaintiff argues that Allergan's repeated disclosures of a possible association between breast implants and ALCL were misleadingly incomplete, because—putting aside whether breast implants and ALCL are definitively linked or not—Allergan's "boilerplate," generalized statements understated the extent to which Allergan's products were *specifically* associated with reported cases of BIA-ALCL. (*See* Pl.'s Opp. at 12–13; 15–16.) Defendants' disclosures are especially misleading, Plaintiff contends, given how the Company repeated the same stock phrase in its annual report for years—that "a breast implant manufacturer *that is not affiliated with the Company*" was subject to "negative reports from regulatory authorities in Europe" (Connolly Decl. Exs. 2, 3, 5, 6, 9, 11, 14, 20, 29) (emphasis added). According to Plaintiff, this allegedly created the false impression that Allergan's breast implants were no more likely to be found in individuals suffering from ALCL than other companies' products. (Pl.'s Opp. at 15.) So too, Plaintiff argues, was Defendants' public statement concerning the "safety profile" of Allergan's implants (CAC ¶¶ 159–61) misleading, because it "fail[ed] to cite to[] and acknowledge more recent studies from 2016 and 2017[] that definitively conclude that Allergan's implants are associated with more cases than any other type of textured implant—by far" (*id.* ¶ 161).

Perhaps because Plaintiff devoted so much energy to the straw man that Allergan's breast implants were "definitively linked" to ALCL, Defendants did not respond to this more nuanced allegation.

But, in this instance, Plaintiff is absolutely correct.

"Even when there is no existing independent duty to disclose information, once a company speaks on an issue or topic, there is a duty to tell the whole truth." *Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 250 & n.3 (2d Cir. 2014). As the Second Circuit reiterated earlier this year, even a statement that is literally true when viewed in isolation can be misleading in context if it leaves investors with a false impression. *See, e.g.*, *Cigna*, 918 at 63 (2d Cir. 2019) (quoting *Operating Local 649 Annuity Tr. Fund v. Smith Barney Fund Mgmt. LLC*, 595 F.3d 86, 92 (2d Cir. 2010)).

Allergan's disclosure that "reports [] have suggested a possible association between anaplastic large cell lymphoma and breast implants" (Connolly Decl. Exs. 14, 20, 29) does not necessarily suffice to insulate the company from liability, because it very well could have left investors with the impression that other companies' breast implants are just as likely to be found in women with BIA-ALCL as were Allergan's products. And Allergan's subsequent statement that "another breast implant manufacturer that is not affiliated with the Company" is subject to "negative reports from regulatory authorities in Europe" very likely could have reinforced that impression.

Assuming the allegations in the CAC are true, that impression would be misleading.

In March 2015, for example, a team of researchers concluded that, out of 173 cases of BIA-ALCL, Allergan's Biocell implants accounted for 56% of all cases in which the type of implant was known. (*Id.* ¶ 75.)

In April 2017, two doctors from the M.D. Anderson Cancer Center in Houston published an article that found that, of the total number of BIA-ALCL cases reported to the University of Southern California's ALCL Tracking Reporting system, 56% of them involved

Allergan/Inamed/McGhan implants, while the total number of BIA-ALCL cases reported to the FDA MAUDE database, 80.3% involved Allergan/Inamed/McGhan implants. (*Id.* ¶ 91.)

In October 2017, another team of researchers who analyzed all cases of BIA-ALCL in Australia and New Zealand from 2007 to 2016 found that Allergan's Biocell salt textured implants accounted for 58.7% of the implants used, which meant that the risk of developing BIA-ALCL when one used Biocell implants was 14.11 times greater than when a leading competitor's textured implants were used. (CAC ¶¶ 100–01.)

And on January 4, 2018, another team of researchers from the Netherlands found that, between 1990 to 2016, there were twenty-three known cases of BIA-ALCL—twenty-two of which involved Allergan/Inamed/McGhan implants. (*Id.* ¶ 103.)

All of this is to say that one could reasonably infer from the foregoing that Allergan's implants were more closely associated with the incidence of BIA-ALCL than other breast implants on the market. But Allergan's disclosures suggest the opposite.

Whether Allergan's breast implants *in fact* are more closely associated with BIA-ALCL is a question that goes beyond the scope of this motion. But Defendants are wrong to argue that CAC fails to state a claim for securities fraud.

Indeed, the Second Circuit's decision in *Meyer* is dispositive.

In that case, the defendant-corporation, JinkoSolar, made various disclosures about the "pollution potential" of JinkoSolar's business and applicable Chinese environmental regulations and standards. 761 F.3d at 247. As to the company's environmental efforts, the company represented, among other things:

> We have installed pollution abatement equipment at our facilities to process, reduce, treat, and where feasible, recycle the waste materials before disposal, and we treat the waste water, gaseous and liquid waste and other industrial waste produced during the

> manufacturing process before discharge. We also maintain environmental teams at each of our manufacturing facilities to monitor waste treatment and ensure that [these] waste emissions comply with [People's Republic of China] environmental standards. Our environmental teams are on duty 24 hours. We are required to comply with all PRC national and local environmental protection laws and regulations[.]

Id.

JinkoSolar's "prophylactic" efforts to prevent environmental hazards proved inadequate. *Id.* Over the ensuing year, the company was cited repeatedly by a Chinese environmental regulatory body for failing to properly dispose of hazardous waste and emitting high levels of fluoride. *Id.* at 247–48. At one point, local residents even surrounded the company's solar cell plant and "angrily demonstrated outside the facility following a massive die-off of fish over the previous month in the river flowing immediately adjacent to the plant." *Id.* at 249. "[B]y the time the dust had settled," Jinkosolar's stock lost 40% of its value. *Id.* A securities lawsuit followed, in which plaintiffs alleged that, at the time that the defendants furnished the above statement, they already knew about substantial environmental problems at the company's solar plant but failed to disclose those issues; instead, they offered generalized statements about the company's efforts to comply with applicable environmental regulations, which gave investors the false impression about the state of play at the company's Chinese factory.

The district court dismissed the complaint, finding that defendants failed to make any material misstatements or omissions. *Id.* The Second Circuit reversed—not strictly because of what the defendants said in their environmental disclosures (all of which "may technically [have] be[en] true," *id.* at 251), but because of what they failed to say along with those disclosures: that their "prophylactic steps . . . to prevent serious ongoing pollution problems" had not been working, *id.* at 250. The court concluded that a trier of fact could infer that the defendants'

failure to disclose certain environmental problems "renders misleading the comforting statements in [JinkoSolar's] prospectus about [its] compliance measures." *Id.* at 251.

The same concept applies here. While Allergan cannot be held liable for securities fraud simply because certain of its breast implants have been recalled, it could be held liable for securities fraud if a trier of fact were to conclude that Defendants' generalized statements about a possible association between breast implants and ALCL gave investors false comfort that Allergan's breast implants were no more closely linked to the cancer (or were less linked) than other products on the market.

In summary, Plaintiff's assertion that Defendants are liable for securities fraud for failing to adequately disclose a "definitive link" between Allergan's breast implants and ALCL fails, because, as pleaded, no such definitive link has been established. However, to the extent Defendants' disclosures gave investors a false impression that Allergan's implants were no more linked with BIA-ALCL than other implants, Defendants' motion to dismiss is denied.

ii. Misrepresenting the Extent to Which Allergan Complied with Regulatory Requirements and Shared Information with the FDA

Plaintiff alleges that Allergan submitted a "significant" number of AERs using an inaccurate manufacturer name and filed ASRs to report multiple adverse events at once (CAC ¶¶ 120–21), thereby rendering false Defendants' statements concerning the Company's adherence to applicable regulations, *supra* at II(E)(2). A closer look at the documents relied upon by Plaintiff in making these claims renders each implausible.

Regarding Allergan's allegedly defective AER submissions, Plaintiff identifies two. (Walsh Decl. Exs. P, R). One AER identifies Allergan as the manufacturer. (*Id.* Ex. R). The other is dated August 7, 2008—nearly a decade before the Class Period—and relates to "right

side inflation," not ALCL. (*Id.* Ex. P.) Plaintiff's contention that Defendants "engag[ed] in this practice" during the Class Period "to hide from the public at large the mounting number of AERs reflecting BIA-ALCL associated with its Implants" (Pl.'s Opp. at 5) is, therefore, unconvincing.

Regarding Allergan's use of the ASR program, the very article on which Plaintiff relies in arguing that Allergan had been "bury[ing] evidence of ruptures and other injuries" (CAC ¶ 121(citing article)) is an article that does not actually mention Allergan or its breast implants. More to the point, this article states the FDA encouraged manufacturers to file ASRs in order to reduce "redundant paperwork" and "'allow[] the FDA to more efficiently review adverse events.'" (Connolly Decl. Ex. 30 at 3, 7 (cited in CAC ¶ 121 & n.44).) Obviously, use of the ASR program was perfectly lawful; Plaintiff alleges no particularized facts indicating that Defendant used ASRs after the FDA shut down the program, which would, if true, plausibly support a claim that Allergan misrepresented the company's "compliance with applicable regulations relating to the reporting of BIA-ALCL to the FDA." (CAC ¶ 86.)

Plaintiff has not plausibly pleaded that Defendants misrepresented Allergan's adherence to its regulatory obligations.

iii. Misrepresentations Concerning Allergan's Efforts to Study a Possible Connection Between Breast Implants and ALCL

Plaintiff alleges that Defendants' various representations that Allergan was actively working to help advance the knowledge of BIA-ALCL, *see supra* at II(E)(1)(3), were false. In support of this claim, it points to three categories of allegations: that (*i*) Allergan sought and received permission to terminate post-approval studies of its breast implant products; (*ii*) CW2 alleges that he witnessed firsthand how Allergan's breast implant research team deliberately

avoided studying BIA-ALCL; and (*iii*) the Company shut down its Santa Barbara facility, the site of its breast implant research and development team.

Insofar as the first of these assertions is concerned: The representation that Allergan obtained FDA permission for early termination of its post-approval studies is a true representation. The Plaintiffs allege no facts that would, if proved, demonstrate that Allergan lied to or misled the FDA or anyone else in order to obtain early termination permission. In the absence of such an allegation, the fact that the relevant regulatory agency authorized early termination—which was fully disclosed—means that the investing public was told everything it needed to know.

Plaintiff effectively alleges that, if Allergan were really devoted to learning the truth about the association between its breast implants and BIA-ALCL, it would have plowed on with its post-approval studies for the full ten years—or, put otherwise, alleges that Allergan should not have sought early termination. But that is a policy argument, not the stuff of a 10(b)(5) case.

The common thread tying the other two allegations together is that Allergan misled investors by asserting that it supported BIA-ALCL research when it did not, in fact, conduct any in-house studies of the issue.

But the CAC does not identify a single statement in which Defendants represented that the Company *was* studying BIA-ALCL. What Allergan publicly represented is that it was "actively working to help advance the knowledge of" BIA-ALCL and that it "has been fully committed to investing and supporting work to further understanding" BIA-ALCL. Those statements are not inconsistent with the notion that Allergan did not itself conduct studies of the BIA-ALCL link. And the CAC identifies numerous examples that prove those representations to be true. As Plaintiff itself alleges, Allergan sponsored external research of BIA-ALCL;

dispatched its employees—both lower-level and senior management—to conferences discussing BIA-ALCL; conducted surgeon education meetings and webcasts; partnered with other organizations (including the American Society of Plastic Surgeons and International Society of Aesthetic Plastic Surgery) to distribute BIA-ALCL education materials; and collaborated with the FDA and other manufacturers to create the NBIR to strengthen oversight of breast implant products. (CAC ¶ 96; Connolly Decl. Ex. 7 at 15 (Allergan Form 8-K); *id.* Decl. Ex. 13 at 7–8 (Marmur's statement to *ABC News 7*) (cited in CAC ¶¶ 8–9, 83–86, 125–26 & n.23); *id.* Ex. 34 at 19–20 (Allergan presentation before FDA Medical Devices Advisory Committee panel dated March 25, 2019) (cited in CAC ¶¶ 176–79); CAC ¶ 113.)

The closest Plaintiff comes to alleging something inconsistent with Allergan's professions of interest in BIA-ALCL research is the broadly worded statement that the company provided to *ABC News 7* at the start of the Class Period: "Allergan is actively working to help advance the knowledge of this disease, understand the association of BIA-ALCL and textured implants, and educate the community, including" by ". . . "supporting ongoing research[.]" (CAC ¶ 84.) Allergan made another, similarly broad statement towards the end of the Class Period, in which it stated that the Company, "is and has been fully committed to investing in and supporting work to further understand the increase awareness of breast-implant associated ALCL." (CAC ¶ 162.) Neither of those statements qualifies as an affirmative assertion that Allergan was conducting in-house research on the topic.

Accordingly, even accepting as true Plaintiff's assertion that Allergan conducted no independent research of its own into BIA-ALCL, and closed down (for whatever reason) the facility at which in-house research was conducted, the Company is alleged to have done a number of other things that would have the effect of advancing knowledge and understanding

about BIA-ALCL—just as Defendants publicly represented during the Class Period. To the extent Plaintiff's non-disclosure claim rests on this basis, it is dismissed as implausible.

2. Scienter

In addition to alleging facts showing an actionable omission, to plead a viable Section 10(b) claim, a plaintiff must state with particularity facts giving rise to a strong inference that the defendants acted with scienter. *See* 15 U.S.C. § 78u-4(b)(2)(A); *Tellabs*, 551 U.S. at 313. "Under this heightened pleading standard for scienter, a 'complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.'" *Slayton v. Am. Exp. Co.*, 604 F.3d 758, 766 (2d Cir. 2010) (quoting *Tellabs*, 551 U.S. at 324). A litigant may satisfy this pleading requirement by alleging facts showing either motive and opportunity to commit fraud or strong circumstantial evidence of conscious misbehavior or recklessness. *ECA, Local 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198–99 (2d Cir. 2009).

The CAC adequately alleges strong circumstantial evidence of fraudulent intent or recklessness. As pleaded, the Company and its senior executives were well aware of the growing body of evidence suggesting that Allergan's implants were more closely associated with ALCL than others—indeed, they furnished various statements about the issue during the Class Period. Yet Defendants failed to update their allegedly stale disclosure that "reports [] have suggested a possible association between" ALCL and breast implants, which included "negative reports from regulatory authorities in Europe related to a breast implant manufacturer that is not affiliated with the Company." (Connolly Decl. Exs. 14, 20, 29.) As alleged, Defendants knew or recklessly disregarded that their positive statements commenting on a "possible association"

between breast implants and ALCL, while technically true, downplayed the specific risk that might be associated with Allergan's products.

This strong inference of scienter is particularly compelling when juxtaposed with the mounting media reports on BIA-ALCL—especially the *New York Times*'s May 2017 article titled, "A Shocking Diagnosis: Breast Implants 'Gave Me Cancer.'" That report specifically observed that Allergan's implants "seem to be associated with more cases than other types, possibly because they are more deeply textured and have more surface area to stick to." (*See* Denise Grady, *A Shocking Diagnosis: Breast Implants 'Gave Me Cancer'*, N.Y. Times (May 14, 2017), https://www.nytimes.com/2017/05/14/health/breast-implants-cancer.html (cited in CAC ¶ 93).) Even after they were publicly confronted with this allegation, Defendants failed to update their risk disclosures.

Accepting the allegations as true and drawing all inferences in Plaintiff's favor, Defendants knew or, at minimum, were reckless about the potentially misleading nature of their public statements. Plaintiff has plausibly pleaded scienter.

3. Reliance

To recover for a violation of Section 10(b) and Rule 10b-5, a private securities plaintiff must demonstrate that she relied upon the alleged misrepresentation or omission in deciding to buy or sell a security. *See, e.g., Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 206 (1976). The most direct way for an investor to demonstrate reliance is by showing *acutal reliance—i.e.*, that she was aware of the company's allegedly false statement and bought or sold a security based on that fraud. *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 810 (2011); *see also Waggoner v. Barclays PLC*, 875 F.3d 79, 93 (2d Cir. 2017). However, in recognition of the fact that demonstrating actual reliance may prove particularly tricky in a securities fraud suit, the

Supreme Court has found that litigants can make the requisite showing of reliance indirectly as well.

Where the alleged fraud involves primarily misrepresentations, plaintiffs are entitled to a rebuttable presumption of reliance if the misrepresentation was material, if it was publicly known, if the stock traded on an efficient market, and if the plaintiff traded the stock between the time the misrepresentation was made and when the truth was revealed. *Basic*, 485 U.S. at 248 n.27, 250; *see also Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 268 (2014). Where the alleged fraud involves primarily omissions of a material fact, the investor to whom the duty was owed need not provide specific proof of reliance. *Affiliated Ute Citizens of Utah v. United States*, 306 U.S. 128, 153–54 (1972); *see also Stoneridge Inv. Partners, LLC*, 552 U.S. 148, 159 (2008).

Plaintiff seeks to avail itself of *Affiliated Ute*'s presumption of reliance because, it contends, this case primarily involves Allergan's failure to disclose that there was mounting evidence that Allergan's breast implant products were more closely associated with ALCL. (Pl.'s Opp. at 24.) Defendants counter that *Affiliated Ute*'s presumption of reliance does not attach where, as here, Allergan and other third parties "extensively disclosed" the very facts that serve as the basis of the alleged fraud. (Defs.' Mem. of Law in Supp. Mot. to Dismiss ("Defs.' Br.") at 23, dated May 24, 2019, Dkt. No. 74.)

Defendants are wrong—both factually and legally.

As a factual matter, Defendants did not "explicitly disclose the very risks about which Plaintiff claims to have been misled." (Defs.' Br. at 23 (citing *Ashland Inc. v. Morgan Stanley & Co.*, 652 F.3d 333, 338 (2d Cir. 2010) (internal quotation marks and alterations omitted)).) Nowhere did Defendants disclose that a number of reports indicated that certain of Allergan's

breast implants were *more* closely associated with ALCL than other breast implants. For the reasons explained above, Defendants' generalized disclosures of a "possible association" between breast implants and ALCL do not suffice.

As a legal matter, Defendants are incorrect in arguing that, "through minimal diligence, [Plaintiff] should have discovered the conduct that constituted the alleged fraud." (Defs.' Br. at 23 (citing *In re UBS Auction Rate Sec. Litig.*, No. 08 Civ. 2967 (LMM), 2010 WL 2541166, at *22 (S.D.N.Y. June 10, 2010), *Tanzanian Royalty Expl. Corp. v. Crede CG III, Ltd.*, No. 18 CIV. 4201 (LGS), 2019 WL 1368570, at *8 (S.D.N.Y. Mar. 26, 2019) (internal quotation marks omitted)).) A truth-on-the-market defense—an "intensely fact-specific" inquiry as it is—is not applicable unless the truth conveyed to the public was done with a degree of intensity and credibility so as to counter-balance any misleading impression created by the defendants' fraud. *See Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 167 (2d Cir. 2000).

Moreover, *UBS Auction Rate* and *Tanzanian*—both of which were market manipulation cases, not mere fraudulent misstatement cases—are wholly inapposite. In those cases, the defendants' manipulative conduct was disclosed directly and completely in their securities filings. *See In re UBS*, 2010 WL 2541166, at *22; *Tanzanian*, 2019 WL 1368570, at *8. Here, much of the information underlying Plaintiff's claim was published either in academic or medical journals—some of which were behind a paywall (CAC ¶¶ 64, 75, 76, 92)—or contained in regulatory notices, some of which were published overseas (and in different languages). The securities laws require investors to read securities filings and other readily available information. "But case law does not support the sweeping proposition that an issuer of securities is never required to disclose publicly available information." *Litwin v. Blackstone Grp., L.P.*, 634 F.3d

706, 718 (2d Cir. 2011). The factual allegations underling the CAC can hardly be deemed readily available.

Plaintiff has plausibly pleaded reliance.

4. Loss Causation

A plaintiff suing for securities fraud must establish that the alleged fraud was the cause of its investment loss. 15 U.S.C. § 78u-4(b)(4); *Dura Pharm., Inc. v. Broudo,*544 U.S. 336, 338 (2005). Merely purchasing securities at an inflated price will not suffice. *Dura Pharm.*, 544 U.S. at 342. Rather one must allege "that the subject of the fraudulent statement or omission was the cause of the actual loss suffered, *i.e.*, that the misstatement or omissions concealed something from the market that, when disclosed, negatively affected the value of the security[.]" *Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 172 (2d Cir. 2005).

On a motion to dismiss, all that is required is "some indication of the loss and the causal connection that the plaintiff has in mind." *Dura Pharmaceuticals*, 544 U.S. at 347. That indication may be established by pleading either a corrective disclosure or a materialization of a concealed risk. *In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 511 (2d Cir. 2010).

Here, Plaintiff proceeds under the latter theory. Accordingly, the CAC must adequately allege that the loss was both foreseeable and caused by the materialization of a concealed risk. *Lentell*, 396 F.3d at 173. A loss is foreseeable if it is "within the zone of risk concealed by the misrepresentations and omissions alleged by the disappointed investor." *In re Flag Telecomm. Holdings, Ltd. Sec. Litig.*, 574 F.3d 29, 40 (2d Cir. 2009) (quoting *Lentell*, 396 F.3d at 173).

Plaintiff alleges that the non-renewal of Allergan's CE Mark and subsequent recall of Allergan's breast implants represented the materialization of the previously undisclosed risk that the Company's products could be recalled because of a possible link to BIA-ALCL, thereby

causing the 7% stock drop that occurred on December 19, 2018. (CAC ¶ 167.) In support of this contention, it pleads that, just weeks before ANSM took action, *ABC News* reported that the regulator was planning to hold public hearings about BIA-ALCL and that, in the interim, would recommend against the use of textured implants. (CAC ¶ 115.)

Under *Dura*, Plaintiff has plausibly pleaded loss causation. Whether Allergan's stock price fell because of the revelation of a fraud (as opposed to a negative development affecting the Company's business) is a fact question.

B. The Motion to Dismiss the Section 20(a) Control Person Claim is Denied, Because Plaintiff Has Plausibly Alleged a Section 10(b) Claim

Section 20(a) holds liable any persons who "control" those found primarily liable under the Exchange Act. 15 U.S.C. § 78t(a)); *accord* ATSI, 493 F.3d at 108 (elements of control person liability). Here, the CAC plausibly alleges an underlying violation of the securities laws. Accordingly, Plaintiff's Section 20(a) claim cannot be dismissed.

CONCLUSION

Based on the foregoing, Defendants' motion to dismiss is granted in part and denied in part.

The Clerk of Court is respectfully directed to terminate the open motion at Dkt. No. 72.

The constitutes the "written" decision and order of the Court.

Dated: September 20, 2019
New York, New York

Chief Judge

BY ECF TO ALL PARTIES